

Cambridge University Press  
0521605245 - Health Law and the European Union  
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## Part One

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## 1

## Introduction

### I. Health law and the European Union

In 1996, a young British woman, Diane Blood, sought to use sperm which had been collected from her recently deceased husband, Stephen Blood, while he was critically ill with meningitis. Although Stephen and Diane Blood had discussed having a family, crucially, Stephen had not given written consent for the taking of his sperm. In English law, the use of the sperm was prohibited under the UK Human Fertilisation and Embryology Act 1990.<sup>1</sup> However, relying on Diane Blood's EU law right to receive medical treatment in another Member State,<sup>2</sup> the English Court of Appeal granted Diane Blood permission to receive the treatment she sought in Belgium. Diane Blood subsequently gave birth to a son, Liam.<sup>3</sup> In 2003, another British woman, Yvonne Watts, sought a hip replacement for her arthritic hip in France, to avoid an NHS waiting list.<sup>4</sup> She then attempted to reclaim the cost of her treatment from her local National Health Service Trust. The Trust refused, and Yvonne Watts brought an action in the English High Court, challenging their decision, claiming that it was *ultra vires*, contrary to provisions of the UK Human Rights Act 1998, and contrary to her free movement rights under EU law. She lost on the facts, but the case is currently subject to an appeal and has been referred to the European Court of Justice.

In both these situations, the law of the EU had a direct impact on the legal entitlements to health care of "citizens of the European Union". In the case of Diane Blood, EU law helped her to receive the medical treatment she sought, in the face of clear British law providing that such treatment would be illegal in the UK. The EU's legal regime came into conflict with the UK's regulatory regime on the matter, with the consequence that, for Diane Blood at least, the UK's regulatory regime ceased to

1 *R v Human Fertilisation and Embryology Authority, ex parte Blood* [1997] 2 All ER 687; and see generally T. Hervey, "Buy Baby: The European Union and Regulation of Human Reproduction" 18 OJLS (1998) 207; D. Morgan and R. Lee, "In the Name of the Father? Ex parte Blood: Dealing with Novelty and Anomaly" 60 MLR (1997) 840.

2 Articles 59 and 60 EC.

3 For further discussion of the *Blood* case, see chapter 4.

4 *R (on the application of Yvonne Watts) v Bedford Primary Care Trust, Secretary of State for Health* [2003] EWHC 2228 (Admin), 1 October 2003.

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be applicable. This story led us to the subject of enquiry and main research question for this book.

Health is not an area which is traditionally regarded as falling within the remit of EU law. There is no single entity entitled “European health law”. However, as the Diane Blood story made clear, EU law may have an effect on national health law and policy. We wondered to what extent, and in what ways, EU law might have such an effect. The deceptively simple question – “how does EU law affect national health law and policy?” – led us to a very wide-ranging enquiry. If one adopts a broad definition of health law and policy, scarcely any part of that field remains completely untouched by EU law. We are interested not simply in the kind of “hard legal” effect at issue in the cases of Diane Blood or Yvonne Watts, in which justiciable rights emanating from EU law change the health law of Member States. We are also interested in the many ways in which EU and national legal norms interact in the health field, to produce results that might not have been produced without the existence of the EU. Of course, it is not possible to determine clear cause and effect in this way. Changes to national health laws and policies may come about as a result of many pressures, ranging from local to global.<sup>5</sup> The EU institutions do not act in isolation from international bodies, such as the World Health Organisation or the Council of Europe, and, where appropriate, we have explored these interactions.<sup>6</sup> However, our principal aim was simply to elaborate, and seek to understand, the contribution of the institutions of the EU, with its unique legal order, to national health laws and policies in the Member States of the EU.

The Community’s developing competence in the health field (Article 152 EC) formed a starting point for our analysis. However, it rapidly became clear that investigating the impact of activities of the EU institutions on health law and policy would involve consideration of many other areas of Community competence, including, at least potentially, the law of the internal market in goods and services, freedom of movement of persons (patients and medical professionals), the common agricultural policy, transport policy, environmental policy, consumer protection, competition policy, research and technological development, development cooperation, and even some elements of the employment strand of social policy.<sup>7</sup> We would also need to include discussion of the EU’s power to finance activities, such as educational programmes or medical research, as a potential force for convergence of national health systems.

Our research question was not to determine whether there should be a “European health law”, in the sense of a harmonised set of health care or medical entitlements, applicable across the whole of the EU, determined by institutions at EU level. It is

5 See, for example, R. Freeman and M. Moran, “Reforming Health Care in Europe” 23 *West European Politics* (2000) 35.

6 See generally S. Fluss, “The Development of National Health Legislation in Europe: The Contribution of International Organisations” 2 *European Journal of Health Law* (1995) 193.

7 For further elaboration, see chapter 3, nn 83–90.

important to emphasise that, in this book, we are not setting out an agenda of what the EU *should* engage in. Rather, we are attempting to examine just how the EU has engaged, is engaging, and is likely to engage, with health policy and, especially, health law.

Nor was our research question to determine whether there is such a “European health law”. It is already clear that the EU does not currently have “its own” health law or policy in this sense. In fact, as will become clear, we regard such a conceptualisation of the EU’s legal order as fundamentally misconceived and unhelpful. Rather, we prefer to conceptualise the EU as a “constitutionalised” non-national polity or system of governance, within which institutions and other actors interact to formulate policy, determine legal norms, and allocate resources. While national (and sub-national) institutions within this polity are the primary locus for formation of health law and policy, and indeed of delivery of health care entitlements, the EU institutions also have a role to play.

Of course there are significant differences between the Member States of the EU in the provision of health care and the organisation of its delivery, and these differences will increase as the EU enlarges towards the east.<sup>8</sup> Moreover, even *within* some Member States, such differences may exist, in particular where responsibilities for health care are devolved to regional or other sub-national institutions. These differences arise for many interrelated reasons, including the historical, social, political and cultural. Each Member State of the EU preserves its own national health policy, as part of its unique social policy. These differences translate into differences in approach with respect to regulation and to interpretation of legal measures supporting national health systems. However, at least at a level of abstraction, “fundamental values”, such as the sanctity of life,<sup>9</sup> dignity,<sup>10</sup> autonomy,<sup>11</sup> privacy, justice, and solidarity,<sup>12</sup> may be said to underpin all health regimes within the EU although the interpretation of those values may differ considerably in practice.

One key element of the EU’s role may be seen in the protection of such “European values” inherent in European national health systems, in the context of increasing international economic pressures. Although each Member State of the EU preserves its own unique national health policy, at a more abstracted level it may be possible

8 See below nn 95–101.

9 Respect for the sanctity of life is common across a wide range of jurisdictions and faiths, although what precisely constitutes “sanctity of life” has been the subject of much debate and discussion: see generally J. Glover, *Causing Death and Saving Lives* (Harmondsworth: Penguin, 1990); P. Singer, *Rethinking Life and Death; the collapse of our traditional ethics* (Oxford: OUP, 1995); J. Keown, “Restoring Moral and Intellectual Shape to the Law After *Bland*” 113 LQR (1997) 481.

10 Dignity itself is a notoriously difficult concept to define. For a comprehensive and incisive examination of the literature surrounding the definition of dignity and an attempt to refine a workable concept, see D. Beylveland and R. Brownsword, *Human Dignity in Bioethics and Biolaw* (Oxford: OUP, 2001).

11 See e.g. J. Harris, *The Value of Life* (London: Routledge and Kegan Paul, 1985); R. Gillon, “Autonomy and Consent” in M. Lockwood, ed, *Moral Dilemmas in Modern Medicine* (Oxford: OUP, 1985).

12 For further discussion, and references to some relevant literature, see chapter 10.

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to discern principles, values, preferences and orientations that are distinctively “European”, as opposed to, say, American or Japanese. To the extent that such principles are articulated through EU measures, these elements of national health systems may find some protection from the encroachment of internationalisation. Some of these values may be given specifically legal protection in the EU’s legal order, for instance, by seeking to articulate them as human rights, or by adopting cautious, risk-averse regulatory measures for key health determinants such as food. In this sense, *but in this sense only*, we would have to admit that we are broadly supportive of such an emerging “European health law”.

Before we can begin our investigation, we need to set some parameters around our study. Before we can consider how EU law affects “health law” (or indeed, ultimately, whether we can discern the beginnings of a nascent “European health law”), we need to ascertain what we mean by “health law” for the purposes of our analysis. This is the task of this chapter. It is not a comparative law exercise, although we will draw upon comparative literature at various points in the discussion. Indeed, as we shall see, our conceptualisation of health law differs in several respects from the manner in which interactions between law and health are dealt with by some academic commentators in individual Member States.

The chapter proceeds as follows. First, we consider what we mean by “health”. Second, the evolution in the law’s engagement with health in Member States, and its engagement with biomedical ethics, is explored through selected examples. Third, we consider some of the definitional debates as to the disciplinary boundaries involved in the study of the relationship between law and health, as an academic discipline. Fourth, we suggest why “health law”, rather than “medical law” or indeed “health care law”, provides an effective starting point for considering the manner in which the EU engages in this area. All Member States of the EU have a body of “health law”, even though it may not be explicitly recognised as such in the literature. Fifth, we consider fundamental components of health law. Finally, we outline the substantive examples which form the case studies discussed in this book.

### II. What is health law?

We begin by considering just what exactly we mean by “health law”. In a book which addresses itself to both health lawyers and EU lawyers, and seeks to explore the manner in which the EU is affecting health law in the Member States, we need, at the very least, to attempt to clarify what we mean by “health law”. While the nature and the scope of the discipline of health law may seem obvious at first glance, its precise boundaries are in many respects rather fluid. A further difficulty in considering health law is that, although it is the case that many areas, which can be regarded as the component parts of the discipline, have been the subject of considerable legal regulation and academic commentary over decades,<sup>13</sup> there

13 And in some cases centuries.

is rightly a general perception that academic engagement with such issues is still a comparatively recent endeavour.

### What is health?

What are health lawyers concerned with? The obvious answer is, “well, ‘health’, of course!” But what do we mean by “health” for these purposes? In the context of an important discussion of the “right to health”, Montgomery outlined two possible conceptions of “health”: the “engineering model” and the “social model”.<sup>14</sup> The engineering model focuses on the repair of the “defective” human machine. At first sight, such an approach has the great advantage of producing a clear definition of good and ill health. However, as Montgomery himself notes, there are certain difficulties with such an approach. How does one identify when the “machine” becomes defective? Can we ascertain an optimum level of health? Sensitive and controversial classifications may result. For example, consider those who have difficulty conceiving, and seek access to modern reproductive technologies. Should we regard the infertile as “ill”?<sup>15</sup> Or, to take another example, does ascertaining an optimum state of health mean that those who believe that they are suffering trauma because they have a large nose or ears should be able to access cosmetic surgery to make them “beautiful”? As Kennedy so elegantly expressed it, illness,

“a central concept of medicine, is not a matter of objective scientific fact. Instead it is a term used to describe deviation from a notional norm. So a choice exists whether to call someone ill. The choice depends upon the norm chosen and this is a matter of social and political judgment. As the great American scholar Oliver Wendell Holmes remarked at the end of the nineteenth century, ‘the truth is that medicine, professedly founded on observation, is as sensitive to outside influences, political, religious, philosophical, imaginative, as is the barometer to the changes of atmospheric density.’”<sup>16</sup>

The judgment of what constitutes illness, while inherently subjective, is something which, in the past, has been entrusted to the medical profession. But a medical professional determination of what constitutes ill health may not always be effective, conclusive, nor indeed necessarily appropriate.<sup>17</sup>

An alternative approach is to consider what constitutes “health” in the light of international statements such as that provided by the WHO and UNICEF Declaration of Alma Ata, 1978. This provides that:

“health, which is a state of complete physical, mental and social well-being and not merely the absence of disease and infirmity, is a fundamental human right and that the

14 J. Montgomery, “Recognising a Right to Health” in R. Beddard and D. Hill, eds, *Economic, Social and Cultural Rights: Progress and Achievement* (Basingstoke: Macmillan, 1992); and see the further discussion in J. Montgomery, *Health Care Law* (Oxford: OUP, 2002), pp 2–4.

15 See further on this point J. Stone, “Infertility treatment: a selective right to reproduce?” in P. Byrne, ed, *Ethics and Law in Health Care and Research* (Chichester: John Wiley, 1990).

16 I. Kennedy, *The Unmasking of Medicine* (London: Allen and Unwin, 1981), pp 7–8.

17 See further Kennedy, above n 16, pp 10–11, 16.

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attainment of the highest possible level of health is a most important worldwide social goal whose realisation requires the action of many other social and economic sectors in addition to the health sector.”

Taking a broad notion of “health” as the basis for our consideration of health law has the advantage of including the legal rights encompassed by the engineering model. It also has the advantage that it extends beyond those legal measures, to link health law and policy to other social policy fields, such as poverty or social exclusion. Indeed, as Brazier and Glover comment, it may be the case that, in the future, health care law may be subsumed, at least to some extent, under social welfare law.<sup>18</sup> This is because a considerable amount of health care, especially in the context of its provision to vulnerable groups, such as the young, the elderly or those with learning disabilities, is provided at the interface between social care providers (both state and voluntary sector) and health care providers.

Nonetheless, such a broad model is potentially problematic. As Fluss has noted:

“The WHO definition, partially taken up in Article 12 of the Covenant, expressed health in terms of well-being which again is a philosophical concept. In a large part of the world, living standards are so low, and life itself so precarious, that little more can be done to secure or to restore health other than to attempt to reduce disease or infirmity.”<sup>19</sup>

Thus, even a broad definition of “health” may, in practice, lead to considerable problems regarding both the definition and the conceptualisation of the subject area of “health law”. For example, if “health” is “a state of complete physical, mental and social well-being”, how can we determine the practical content of any “right to health”? Such a “right to health” may be found in several international human rights Conventions,<sup>20</sup> including the Council of Europe’s European Social Charter and Revised European Social Charter, and also in a number of national constitutions,<sup>21</sup>

18 M. Brazier and N. Glover, “Does Medical Law have a Future?” in D. Hayton, ed, *Law’s Futures* (Oxford: Hart, 2000).

19 See above n 6.

20 See Universal Declaration of Human Rights 1948, Article 25; International Covenant on Economic, Social and Cultural Rights 1966, Article 12; Convention on the Elimination of all forms of Discrimination Against Women 1979, Article 12; Convention on the Rights of the Child 1989, Article 24; European Social Charter 1961, Articles 11 and 13; Revised European Social Charter 1996, Articles 11 and 13; Convention on Human Rights and Biomedicine 1997, Article 3; Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights (Protocol of San Salvador) 1988, Article 10. See B. Toebes, *The Right to Health as a Human Right in International Law* (Antwerp: Intersentia/Hart, 1999); B. Toebes, “The Right to Health” in A. Eide, C. Krause and A. Rosas, eds, *Economic, Cultural and Social Rights* (The Hague: Kluwer, 2001), p 173.

21 See, for instance, Article 70 D of the Hungarian Constitution; Article 68 of the Polish Constitution; Article 27 of the South African Constitution; Articles 39 (e) and (f), 46 and 47 of the Indian Constitution; section 15 of Article II of the Philippines Constitution. See Toebes (2001), above n 20, p 174; A. den Exter and H. Hermans, eds, *The Right to Health in Several European Countries* (The Hague: Kluwer, 1999).

including, in the EU, Belgium,<sup>22</sup> Finland,<sup>23</sup> Italy,<sup>24</sup> Luxembourg,<sup>25</sup> the Netherlands,<sup>26</sup> Portugal,<sup>27</sup> and Spain.<sup>28</sup> As Gostin and Lazzarini have commented, there are dangers in a broad definition of a “right to health” because it is less likely to have clearly defined content than a narrower definition, and this could severely limit its practical impact.<sup>29</sup> They suggest that the WHO definition is not achievable and, even if it were limited to a reasonable rather than an absolute standard, there would be considerable practical difficulties of implementation. They propose an alternative approach, that the right to health may be regarded as:

“[t]he duty of the state within the limits of its available resources to ensure the conditions necessary for the health of individuals and populations.”<sup>30</sup>

As Gostin and Lazzarini note, many factors which have an impact on an individual’s state of health, such as genetics, behaviour, over-population and climate, are (either totally or partially) beyond governmental control. However, they have argued that it is the state which possesses the power to ensure conditions under which people are healthy, and therefore it is the state which has a responsibility, within the limits of available resources, to intervene to prevent or reduce serious threats to the health of individuals and populations. Nonetheless, they recognise that the main disadvantage with such an approach is that it does not ensure a minimal standard of health. It also sanctions differential responses to threats to health, based upon available economic resources.

Notions of “health” vary according to temporal and geographical context. One need only look at global mortality rates, or mortality rates across time, to illustrate this. Health indicators are also closely linked to economic prosperity, both globally and within a particular state. The more wealthy enjoy better health, and also better health care. As a particular state becomes more wealthy, the provision of health

22 Article 23: “(1) Everyone has the right to lead a life in conformity with human dignity. (2) To this end, the laws, decrees and rulings alluded to in Article 134 guarantee, taking into account corresponding obligations, economic, social and cultural rights, and determine the conditions for exercising them. (3) These rights include, notably: . . . (2) The right to social security, to health care and to social, medical and legal aid.”

23 Chapter 2, section 19 (3): “The public authorities shall guarantee for everyone . . . adequate social, health and medical services and promote the health of the population.”

24 Article 32: “The Republic protects health as a fundamental right of the individual and as a concern of the collectivity and guarantees free care to the indigent.”

25 Article 11 (5): “The law organises social security, health protection . . .”

26 Article 22 (1): “The authorities shall take steps to promote the health of the population.”

27 Article 64 (1): “Health: All have the right to health protection and the duty to defend it and to promote it.”

28 Article 43: “(1) The right to health protection is recognised. (2) It is incumbent upon the public authorities to organise and watch over public health and hygiene through preventive measures and through necessary care and services. The law shall establish the rights and duties of all in this respect. (3) The public authorities shall foster health education, physical education, and sports. Likewise, they shall facilitate adequate utilisation of leisure.”

29 L.O. Gostin and Z. Lazzarini, *Human Rights and Public Health in the AIDS Pandemic* (Oxford: OUP, 1997).

30 Gostin and Lazzarini, above n 29, p \*\*.

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services will change focus, to include elements such as cosmetic surgery that may be less closely related to “fixing the defective human machine”. Gostin and Lazzarini’s definition of the “right to health” recognises that conceptualisations of good health are dynamic in nature.

Further, it must be borne in mind that our conceptions of health are subject to constant revision due to technological developments. To try and identify one standard of “health”, even across the (relatively homogenous) EU, is exceedingly difficult to undertake. It is particularly problematic in the light of the accession of states from central and Eastern Europe.<sup>31</sup> However, at the same time as noting this diversity, we need also to consider prospects for the development of a more consistent standard of “health”, in the light of the developing globalisation of medicine and science.<sup>32</sup>

While the links between globalisation and health care are complex, it is certainly the case that globalisation may drive standards up. As Adlung has argued:

“Globalisation in the form of increased mobility and enhanced information may prompt more governments to consider the case for domestic regulatory adjustment. Economic growth has enabled large segments of the population not only to compare their supply situation with that of other countries, but to act accordingly and, if need be, move abroad.”<sup>33</sup>

While, in practice, such mobility tends to be amongst the affluent, the potential for the “race to the top” should not be underestimated, and can be also seen in terms of some of the debates regarding quality of health care provision, in the context of mobility of state-funded patients within the EU.<sup>34</sup>

Taking into account all of the above, for the purposes of this book, we regard “health” as centrally focussed upon the individual, and consequently upon an “engineering model”. However, we are also inspired by the insight that the obligations of states to protect human health apply not only to the protection of the health of individuals, but also to the health of populations, and that “health” can be collectively determined. We recognise that the boundaries of individuals, and indeed societal, conceptions of “health” and “illness” are fluid, and in many instances highly subjective, and that this precludes an all-embracing definition of “health”. We now turn to examine how “health law” has emerged as a discipline.

31 A first wave of 10 “accession states” (Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia) signed an Accession Treaty at Athens in April 2003. If ratified by all the accession states, and the current Member States of the EU, this will enter into force on 1 May 2004, at which point the EU will enlarge from the current 15 Member States to 25 Member States. The other “candidate states” Bulgaria and Romania aim to join the EU in 2007; Turkey still needs to strengthen its human rights protection. See further chapter 10.

32 D. Morgan, *Issues in Medical Law and Ethics* (London: Cavendish, 2001), pp 27–32 and see 8(3) *eurohealth* (2002) which devotes a major part of this issue to a discussion of globalisation.

33 R. Adlung, “Health services in a globalising world” 8(3) *eurohealth* (2002) 18.

34 See further chapter 4.

## The evolution of law's engagement with health

Just why is the law concerned with health and its regulation? There are a number of reasons. First, the interface of law with health can be seen as a means of protecting the collective public interest. Public health law, considered in chapter 9, is a part of all legal systems. The state is concerned with the legal regulation of disease, and the use of legislative measures to detain individuals, because they are regarded as a danger to public health, has an ancient history.<sup>35</sup> As we shall see in chapter 6, health professional regulation has been undertaken for centuries across the Member States of the EU, bolstered by the state through legislative measures.

Nonetheless, it is still the case that “health law” is regarded as being a young academic discipline. The engagement of the law with legal regulation of health has speeded up dramatically across the various Member States of the EU over the last century. There are several perceptible triggers for this evolution of the discipline.

At a basic level, lawyers have become more interested in health because there was simply more litigation. Take, for example, the well-documented rise of medical malpractice litigation internationally. In his introduction to Giesen's treatise on *International Medical Malpractice Law* in 1988, Lord Kilbrandon quoted from the judgment given in a Scottish case, *Farquhar v Murray*, in 1901:<sup>36</sup>

“This action is certainly one of a particularly unusual character. It is an action of damages by a patient against a medical man. In my somewhat long experience I cannot remember having seen a similar case before.”

For the next 80 years, litigation across Europe against health professionals continued to be limited.<sup>37</sup> As Brazier and Glover note, discussing the English position:

“Perusal of the Law Reports before 1980 will reveal no more than a handful of reported cases which address either the civil liability of doctors or how the law should respond to controversial problems of medical ethics.”<sup>38</sup>

However, today the situation is very different from the early 1980s. Across Europe as a whole, the volume of litigation in the field of health care has increased significantly. This can be seen as a reflection of the experience in the US of malpractice litigation, where health litigation is “big business” and many lawyers have been

35 See generally L.O. Gostin, *Public Health Law: Powers, Duties and Restraints* (Berkeley and Los Angeles: University of California Press, 2000), preface; L. Johnson, “Defining Public Health” and “Issues of Public Health; Infectious Diseases” in R. Martyn and L. Johnson, *Law and the Public Dimension of Health* (London: Cavendish, 2002).

36 *Farquhar v Murray* (1901) 3F, 859, 862, cited in D. Giesen, *International Medical Malpractice Law* (Tubingen: JCB Mohr (Paul Siebeck); Dordrecht, Boston, London: Martinus Nijhoff, 1988).

37 Kennedy and Grubb, in their introduction to *Principles of Medical Law* 1st ed. (Oxford: OUP, 1998), p vii, have also memorably commented that medical law “was once dominated by medical negligence actions and disciplinary cases arising out of the failure to adhere to the GMC's standards on the ‘three A's’: adultery, alcohol and advertising”.

38 Brazier and Glover, above n 18.